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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,842	10/01/2008	Hans Scheefers	7003/53	4606

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EXAMINER	
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ART UNIT	PAPER NUMBER
1623	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,842	SCHEEFERS, HANS	
	Examiner	Art Unit	
	Lawrence E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 October 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

Applicant is respectfully requested to amend the abstract because the abstract is too generic because it fails to disclose any specific active ingredient or the treatment of any specific disease condition therewith.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

No claims have been cancelled, no claims have been amended, the disclosure has not been amended at page 1, and no new claims have been added as of the date of this Office action. No Information Disclosure Statements (IDSs) have been filed as of the date of this Office action. However, examiner has reviewed the search report attached to the supplied priority document (**WO 2005/054174 A3**) and has cited three foreign patent references cited therein on the attached PTO-892, and has not supplied copies in view of the likelihood that applicant already has copies of same. Examiner has also conduced an inventor's name search in the PALM database and gleaned therefrom two US patents that are now also of record on the PTO-892.

Claims **1-4** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Claims **2 and 4** are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki,* 153 USPQ 678 (Bd. App., 1967) and *Clinical Products, Ltd. v. Brenner,* 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

In claims **2** at line 1 and claim **4** at line 1 the term "use" should be replaced with alternative terminology not derived from the verb
-- to use --.

Claims **1-4** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Factors to be considered:

a) Actual Reduction to Practice? The instant disclosure at page 17, lines 1-3, admits that all of the following examples are prospective, meaning that none of the examples has actually been reduced to practice. In addition, the disclosure suggests that the compounds considered to be appropriate for actual testing are aminooxyacetic acid or salts thereof, a glyceryl diphosphate and a fructose bisphosphate (see page 14 at line 2 and page 16, last sentence), a clear contradiction with the claims.

b) Disclosure of Drawings or Structural Chemical Formulas? The generic formula in claim **1** encompasses a truly vast array of substances none of which have been shown to have been synthesized, a clear indication of a lack of written description. In addition in claim **2**,

directed to pharmaceutical compositions, is defined to include the expected excipients or carriers, a class of substances defined in the disclosure to include "explosives:" see page 11, at line 15. Consultation with a copy of Remington's Pharmaceutical Sciences (18th Ed.) did not produce any index entry for "explosive(s)" or include any indication previously discovered by examiner that such substances have utility in the preparation of pharmaceutical compositions. Examiner also notes claim **1** at lines 3-7, wherein the claim is directed to compounds wherein "r" is 1 and both "X" and "Y" may be simultaneously defined as "-NO_2," thereby defining a substituent group that is likely to render the substances being claimed highly chemically unstable and/or explosive, and therefore very unlikely to have any reasonable medicinal application.

c) Sufficient relevant identifying characteristics? Instant claims **2 and 4**, claims apparently directed to the treatment of diseases, are found to be little more than a laundry list of diseases (claim **2**), or to a laundry list of generic biochemical mechanisms and cells wherein said mechanisms are alleged to be inhibited (claim **4**). The disclosure, not including any medicinal test data whatsoever, fails to support these claims with an adequate written description.

d) Method of making the claimed invention? As noted above, the instant disclosure fails to provide any specific embodiments to exemplify how to make or how to use the instant claimed invention, a clear failure to provide an adequate written description.

e) Level of skill in the art? One of ordinary skill would be expected to be knowledgeable concerning the organic synthesis of pharmaceuticals, the preparation of pharmaceutical compositions therefrom, and the execution of medicinally relevant test protocols to establish medicinal activity if any for the compounds synthesized.

f) Predictability in the art? The art of treating the vast array of disease conditions with each and every one of the vast array of different compounds encompassed by claim **1** is found to be highly unpredictable, particularly when the "disease" to be treated is generically defined in part by terms including "cancer."

In conclusion the instant claims are found to be inadequately supported by the instant written description because the instant written description has fails to provide any specific exemplifications of either how to make (chemically synthesize) any of the claimed active

ingredients, or how to use medicinally any of the vast array of compounds claimed (no medicinally relevant test data has been provided) against an equally vast array of diseases. Applicant is respectfully requested to note that the enablement requirement, and consequently the written description requirement, are elevated in the area of medicinally active compounds and elevated particularly with regard to method claims directed to the treatment of diseases. As an example of the application of this policy applicant is respectfully requested to note *Ex parte Balzarini et al.* (21, USPQ 2d 1892, 1894 (BPAI, 1991)), a decision that in its first opinion stands for the proposition that claims directed to medicinal treatments of diseases in highly unpredictable art areas are properly rejected under 35 U.S.C. §112, first paragraph as lacking adequate enablement, in the absence of sufficient test data in support of the efficacy of the alleged treatment. See MPEP at §2107.03 and other relevant parts of the MPEP cited therein. In addition, examiner respectfully directs applicant to the Supreme Court decision *Brenner v. Manson* (148 USPQ 689 (S. Ct. 1966)), a case that stands for the proposition that a patent is granted for work already accomplished and "... is not a hunting license."

The disclosure is objected to because of the following informalities:

At the beginning of the claims at page 23, the standard claim introducing format for US patent applications is the presence of the term -- We claim -- or herein -- I claim: --.

Appropriate correction is required.

Claims **1, 2 and 4** are objected to because of the following informalities:

In each of claims **1, 2 and 4** are presented lists of alternatives but these lists are not presented in the alternative. In claim **1** this error has the effect of introducing major valence errors into the claim. Examiner respectfully suggests introduction of either "Markush group terminology" or the equivalent "or" terminology into each list of alternatives in order to comport with proper US claim construction and to correct the above noted valence errors. For an example, see claim **1** at line 7, wherein the above noted problem can be solved by insertion of the term -- or -- before the term "-NO_2." Examiner counts at least 7 examples wherein this error occurs in claim **1** alone. Examiner's Note: Markush groups are properly formulated with the term -- selected from the group consisting of [A], [B], ... and [R] --.

In claim **1** the list of alternative substituents representative of variable "Z" (see page 24) are listed following the terminal punctuation at the end of page 24, and therefore are not properly part of claim **1**. U.S. Patent rules require that the entire contents of any claim must be included within the body of the claim (following the claim number) and prior to the terminal punctuation.

In claim **2** the presence of quotation marks at line 4 and at the end of the claim have no significance in US patent claim structure. Did applicant intend a Markush group? See comments above about this and see also the MPEP for guidance concerning the construction of this type of alternative listing in a US patent claim.

Appropriate correction is required.

Claims **1-4** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** in "Formula V," the notation in the right margin (" $S^+ = N$ ") is unclear. Does applicant intend that the Formula V variation of variable "Z" should include the structure shown (a substituent derived from S-adensoylmethionine), or the structure wherein S^+ is replaced with trivalent (amino) nitrogen, or both? Clarification is respectfully requested.

In claim **2** the term "type I diabetes" occurring at line 10 appears to be duplicated by the term "diabetes occurring at lines 17-18. Applicant is respectfully requested to delete one of the two terms to avoid unnecessary duplication.

In claim **3** at lines 4-5, the term "galenically prepared" appears to refer to a standard of an ancient Greek or Roman medical practitioner (Taber's Cyclopedic Medical Dictionary, 19th Ed.). The noted term is also improper in the instant US patent claim because a "pharmaceutical composition claim " is limited in its patentable weight to the identity of the active ingredient(s), the identity of the carrier(s) and/or excipient(s), and the relative proportions thereof, and therefore must exclude process limitations. If applicant desires to claim a process of preparing a pharmaceutical composition, examiner respectfully suggests a separate claim directed to said process as one way to proceed.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-4** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-12*** of U. S Patent No. **7,223,784** (PTO-892 ref. **B**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment (claim ***11***) and the alleged active ingredients are directed to substantially overlapping subject matter when compared with instant claims **1 and 4** in particular.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in

section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claims **1-4** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Eigenbrodt et al. '784** (PTO-892 ref. **B**; US **7,223,784 B2**).

The cited **'784** reference is directed to subject matter that is included within the scope of the compound/pharmaceutical composition claims and the "use" claims, thereby anticipating the instant claimed subject matter. See also PTO-892 ref. **N** for the PCT equivalent.

Claims **1-4** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Upjohn '164** (PTO-892 ref. **M**; GB **971,164**).

The cited **'164** reference is directed to subject matter that is included within the scope of the compound/pharmaceutical composition claims and the "use" claims, thereby anticipating the instant claimed subject matter.

Claims **1-4** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Kisflaudy et al. '778** (PTO-892 ref. **L**; FR **2.150.778**).

The cited **'778** reference is directed to subject matter that is included within the scope of the compound/pharmaceutical composition claims and the "use" claims, thereby anticipating the instant claimed subject matter.

Applicant is also referred to the remaining references cited on the PCT search report **(WO 2005/054174 A3)** and many of the references uncovered in the CAPLUS search notes that also appear to anticipate one or more of the instant claims as equivalents to the specifically cited prior art. Examiner is hopeful that careful amendment to the claims or other appropriate action may provide a basis for moving the prosecution forward.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published

in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
07/19/2009

/Lawrence E. Crane/

Examiner, Art Unit 1623

L. E. Crane
Patent Examiner
Technology Center 1600